IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CHARLES LEON MANOUS, Surviving Spouse and Personal Representative of the Estate of Carol Ann Manous, deceased Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	)	Case No. 5:11-cv-01330-R

DEFENDANT'S RULE 26(A)(2) EXPERT DISCLOSURES

AND NOW COMES Defendant, Mylan Pharmaceuticals Inc. ("Mylan"), by and through its undersigned counsel, and pursuant to Federal Rule of Civil Procedure ("Rule") 26(a)(2), hereby files these Expert Disclosures:

I. RETAINED EXPERTS

1. Robert B. Palmer, Ph.D., DABAT, FAACT
   Toxicology Associates, Prof. LLC
   2555 South Downing St., Suite 260
   Denver, CO 80210
   303-765-3800

Dr. Palmer is a clinical toxicologist, having earned his Ph.D. from the University of Washington in organic/medicinal chemistry in 1994. He is board-certified in Clinical Toxicology by the American Board of Applied Toxicology, and is a Member in the following organizations, *inter alia*: American Association for Clinical Chemistry (Toxicology Division); American Chemical Society (Organic and Medicinal Divisions); American Academy of Forensic Sciences (Toxicology); American Society for Clinical Laboratory Science; and American Academy of Clinical Toxicology. As such, he is an expert in the pharmacokinetics and

pharmacodynamics of drugs. Dr. Palmer has published in peer-reviewed publications on the concept of post-mortem redistribution, with a specific focus on the redistribution of fentanyl after death. He will explain that post-mortem redistribution is a generally accepted scientific principle, such that it is well known that drug concentrations frequently do not remain static after death. Due to the changes in drug concentrations that occur after death, post-mortem fentanyl levels do not reflect ante-mortem drug concentrations. Dr. Palmer will testify that any attempt to rely upon post-mortem toxicology to suggest or infer a problem with a drug delivery system is inherently unreliable. And since post-mortem fentanyl levels are not reflective of delivery rates during lifetime, Dr. Palmer will testify that there is no evidence in this case of a failure or malfunction of the Mylan Fentanyl Transdermal System(s)® ("MFTS") allegedly worn by Carol Ann Manous ("Decedent"). Dr. Palmer will testify further that post-mortem blood level alone cannot be used to establish that Decedent's death was related to fentanyl, based on, *inter alia*, post-mortem redistribution, patient-specific tolerances, and the limitations of the toxicological analysis performed on Decedent's post-mortem blood sample. Dr. Palmer will also offer testimony on the toxicological risks and dangers associated with polypharmacy, as reflected in Decedent's concomitant use of multiple CNS depressant drugs. Finally, Dr. Palmer may offer opinion testimony rebutting any opinions offered on behalf of Plaintiff. The observations and opinions offered by Dr. Palmer in this matter – as summarized in his report, concurrently submitted to Plaintiff – will be based on his review of the materials provided, a continuing review of the relevant scientific literature, and his education and professional experience.

2. Gordon L. Flynn, Ph.D.
   2115 Nature Cove Ct., #202
   Ann Arbor, MI 48104
   734-677-3887

Dr. Flynn is an expert in the fields of pharmaceutics, transdermal drug delivery, and skin permeation. After earning his Ph.D. in Chemistry from the University of Wisconsin in 1965, Dr. Flynn spent his entire career researching and publishing in the field of transdermal drug delivery. The majority of this time – from 1972 until his retirement in 2012 – was spent as a Professor of Pharmaceutics at the University of Michigan. He holds numerous patents in his chosen field, and has published extensively on the topic of transdermal drug delivery, including pioneering studies specifically relating to the delivery of fentanyl through the skin. Dr. Flynn consulted in the design and development of the MFTS. He is familiar with the formulation utilized with the MFTS given his role in its development, and he is expected to offer testimony relating to the design, formulation, testing, and manufacture of the product. It is also expected that Dr. Flynn will testify, among other things, that the MFTS is a monolithic matrix patch that, when properly used, is incapable of leaking or otherwise failing in any manner that would allow it to deliver fentanyl in anything other than its physico-chemically programmed rate. Dr. Flynn will further testify that the MFTS is an inherently safe and effective delivery system when properly used, and he is expected to rebut any theories of product defect offered by Plaintiff. Dr. Flynn may also testify regarding the principles of post-mortem redistribution of fentanyl. Finally, Dr. Flynn will offer the opinion that there is no evidence to support Plaintiff's claim that the MFTS allegedly worn by Decedent was defective or otherwise failed to perform as designed. The observations and opinions offered by Dr. Flynn in this matter – as summarized in his report, concurrently submitted to Plaintiff – will be based on his review of the materials provided, a continuing review of the relevant scientific literature, and his education and professional experience.

3. Mark S. Wallace, M.D.
   Professor of Clinical Anesthesiology
   Chair, Division of Pain Medicine
   University of California San Diego Medical Center

9300 Campus Point Dr., Mail Code 7651
La Jolla, CA 92037
858-657-7030

Dr. Wallace is a medical doctor with a license to practice medicine in the state of California. He is a Board Certified Anesthesiologist with Board Certification in Pain Medicine. As a physician practicing for over 20 years, Dr. Wallace has been responsible for the clinical assessment and management of patients requiring opioid therapy for the treatment of chronic pain and has prescribed transdermal fentanyl patches to patients, where appropriate, since this formulation became available. Dr. Wallace is also a Professor of Clinical Anesthesiology at the Medical School of the University of California, San Diego, and has lectured locally and nationally on the topic of opioid therapy. Dr. Wallace has extensive clinical experience with fentanyl generally and the MFTS in particular. It is anticipated that, if called, Dr. Wallace will testify that the MFTS is a valuable treatment tool in managing pain patients. In addition, he is expected to offer opinions regarding matters associated with Decedent's medical care and treatment, prescription drug use, drug interactions, prior medical conditions, and his experience in the proper prescription and use of the MFTS as a safe and effective delivery system. Dr. Wallace may also offer testimony as to the standard of care and causation as it pertains to selection, prescribing, and dosage of pain medication, all of which are contained in his report. He will offer the opinion that there is no evidence to suggest or support a claim that the MFTS allegedly worn by Decedent was defective or otherwise failed to perform as designed. Instead, Dr. Wallace will testify that fentanyl, along with other medications, was over-prescribed, and Decedent's physicians failed to observe warning signs and dangers of overmedication that were obviously present. Finally, Dr. Wallace may testify as to the adequacy of the labeling provided with the MFTS and in rebuttal of any opinion testimony offered at trial. The observations and

opinions offered by Dr. Wallace in this matter – as summarized in his report, concurrently submitted to Plaintiff – will be based on his review of the materials provided, a continuing review of the relevant scientific literature, and his education and professional experience.

4. Thomas M. Wheeler, M.D.
   Baylor College of Medicine
   Department of Pathology & Immunology
   One Baylor Plaza, Room T203
   Houston, TX 77030
   713-798-4664

Dr. Wheeler is an expert in forensic pathology, serving as a Professor of Pathology at the Baylor College of Medicine since 1981 and as the Chairman of the Department of Pathology and Immunology of the Baylor College of Medicine since 2008. He has also served as the Attending Pathologist in several teaching hospitals in Houston, Texas, including the Methodist Hospital and the Ben Taub General Hospital. Dr. Wheeler serves on the editorial board of, *inter alia*, *Human Pathology*, *American Journal of Surgical Pathology*, and *Archives of Pathology and Laboratory Medicine*. He is a member of, *inter alia*, the American Medical Association, American Society for Clinical Pathology, American Society of Investigative Pathology, Association of Pathology Chairs, and College of American Pathologists. Dr. Wheeler is expected to testify regarding the cause and manner of Decedent's death. Dr. Wheeler will state that, in the absence of an internal autopsy, it is impossible to determine the cause of Decedent's death with any degree of medical certainty. Dr. Wheeler will further explain that, in the context of this case, it is impossible to conclude that fentanyl alone was responsible for Decedent's death due to the well-recognized concepts of tolerance and post-mortem redistribution, as well as the limitations of the toxicological analysis performed on Decedent's post-mortem blood samples. Moreover, Dr. Wheeler will testify that, even if it is assumed that polypharmacy played a role in Decedent's death, it is likely the result of the continued use of fentanyl in large doses in a patient exhibiting

adverse effects, coupled with the concomitant use of other CNS depressant drugs by a patient with severe obstructive sleep apnea. Dr. Wheeler will state that there is no evidence in the record to suggest that the MFTS allegedly worn by Decedent malfunctioned or failed in any way. Finally, Dr. Wheeler will rebut the opinion testimony offered by Plaintiff. The observations and opinions offered by Dr. Wheeler in this matter – as summarized in his report, concurrently submitted to Plaintiff – will be based on his review of the materials provided, a continuing review of the relevant scientific literature, and his education and professional experience.

II. NON-RETAINED EXPERTS

1. Michael Houghton
   Vice President, Research & Development
   Mylan Technologies Inc.
   c/o Clem C. Trischler, Esq.
   Pietragallo Gordon Alfano Bosick & Raspanti, LLP
   One Oxford Centre, 38th Floor
   Pittsburgh, PA 15219
   412-263-2000

Mr. Houghton graduated from Western Michigan University in 1984 with a B.S. in Chemistry. Since then, he has worked his entire career in the field of drug development, first with the Upjohn Company, later with 3M, and now with Mylan Technologies Inc. ("MTI"). His work has focused exclusively on transdermal drug products for the last decade. He is currently the Vice President of Research & Development for MTI. In this position, he has direct oversight responsibility for the research and development of transdermal drug products, the analytical and physical methods used to test those products, and the manufacturing process used to produce these products. He is intimately familiar with and will testify regarding the development and approval history for the MFTS. He will also explain the design, formulation, testing, and manufacturing process for the MFTS. In addition, Mr. Houghton will offer testimony to rebut the suggestion by Plaintiff that alleged defects or deficiencies in the manufacturing process of the

MFTS contributed to Decedent's death. The observations and opinions offered by Mr. Houghton in this matter will be based on his review of the materials provided, a continuing review of the relevant scientific literature, and his education and professional experience.

2. Ronald J. Selders, Pharm.D., MBA
   Senior Director, Product Safety & Risk Management
   Mylan Pharmaceuticals Inc.
   c/o Clem C. Trischler, Esq.
   Pietragallo Gordon Alfano Bosick & Raspanti, LLP
   One Oxford Centre, 38th Floor
   Pittsburgh, PA 15219
   412-263-2000

Dr. Selders is Mylan's Senior Director of Product Safety & Risk Management for North America. In this role, Dr. Selders oversees the pharmacovigilance efforts conducted by Mylan in accordance with all applicable laws and regulations. Since launch of the MFTS in 2005, Dr. Selders and his group have reviewed, evaluated, analyzed, and prepared reports of adverse events reported to Mylan concerning the product, consistent with Mylan's obligations under federal law. As a result of this ongoing review, Dr. Selders will, if necessary, testify that the MFTS is safe and effective when properly used and appropriately managed, and that no safety issue exists with the product, which remains on the market today with FDA's ongoing approval. In this particular case, Plaintiff has identified as exhibits the PSURs and other pharmacovigilance reports prepared by and on behalf of Dr. Selders' group. These reports are irrelevant to Plaintiff's manufacturing defect claim. However, if Plaintiff is permitted to use these irrelevant documents at trial, Mylan will call Dr. Selders to explain these documents and to opine, based on the pharmacovigilance review, that these adverse events do not demonstrate any change in the safety profile of this drug.

3. Marius Tarau, M.D.
   9707 W. 145th Terrace
   Overland Park, KS 66221
   816-881-6609

Dr. Tarau was the medical examiner from the Office of the Chief Medical Examiner of Oklahoma assigned to investigate Decedent's death. His deposition has been taken in this matter, and it is anticipated that he will offer opinion testimony relating to his involvement in the investigation of Decedent's death.

4. Byron Curtis, Ph.D.
   Office of the Chief Medical Examiner of Oklahoma
   901 N. Stonewall
   Oklahoma City, OK 73117
   405-239-7141

Dr. Curtis is the Chief Forensic Toxicologist for the Office of the Chief Medical Examiner of Oklahoma. He signed the Report of Laboratory Analysis regarding testing performed on samples of Decedent's post-mortem blood. His deposition has been taken in this matter. It is anticipated he will offer opinion testimony consistent with the opinions expressed in his deposition and which relate to his evaluation and interpretation of the significance of post-mortem toxicological data.

5. Michael J. Schwartz, M.D.
   650 Hamlet Lane
   Yukon, OK 73099
   405-354-9546

Dr. Schwartz was Decedent's pain management physician who prescribed transdermal fentanyl for her use. It is expected that Dr. Schwartz will testify regarding his care and treatment of Decedent, her medical history, her use of transdermal fentanyl and concomitant medications, and other information as reflected in the medical records received from his office.

III. RESERVATIONS

To the extent necessary, Mylan reserves the right to substitute a new expert in the event that an expert becomes unavailable for trial. Mylan also reserves the right to call any witness identified by Plaintiff. Mylan further reserves the right to add and disclose such additional

witnesses as may be determined to be necessary in response to the disclosure or testimony of other witnesses. Finally, Mylan reserves the right to disclose and call rebuttal witnesses in response to Plaintiff's disclosures, deposition testimony, or evidence presented at trial.

Dated: March 14, 2013

Respectfully submitted,

/s Clem C. Trischler
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Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **Defendant's Rule 26(a)(2) Expert Disclosures** was electronically transmitted to the Clerk of Court using the ECF System for filing on March 14, 2013. Based on the records currently on file, the Clerk of Court will transmit a Notice of Electronic Filing to the following ECF registrant:

L. Mark Bonner, OBA #14541
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By s/ Clem C. Trischler
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